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Title of Invention	
54	A CHEMICAL SUBSTANCE

57	Abstract (not more than 150 words)	Number of Sheets	16
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ABSTRACT

A chemical composition for the treatment of arthritis which includes glucosaminoglycans, glucosamine, methyl sulphonyl methane, ascorbic acid and an suitable excipient.

5 BACKGROUND OF THE INVENTION

This invention relates to a pharmaceutical composition.

Arthritis, a bone degenerating disease, affects the joints of humans and animals. The disease is extremely painful, destroys the mobility of the joints and thereby incapacitates sufferers.

Treatment of arthritis generally consists of administering general analgesics such as aspirin and branded products such as Brufen. Cortico-steroids are also widely used and in severe cases intra-articular injections are administered. Treatment with analgesics only gives temporary relief and often has side effects. Cortico-steroids give longer-term relief by reducing inflammation, but often have severe side-effects and long term use may not be possible.

20 SUMMARY OF INVENTION

This invention is concerned with an alternative composition which may be used for the treatment of bone degenerating diseases like arthritis.

The invention provides a pharmaceutical composition for the treatment of bone degenerating diseases which includes a mixture of glycosaminoglycans, glucosamine and methyl sulphonyl methane.

5 The glucosamine may be provided as a salt derivative of glucosamine.

The glycosaminoglycans may be in the form of pure chondroitin sulphates, mixed glycosaminoglycans, shark or bovine cartilage, other similar animal derivatives, synthetic products or sulphated products.

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The ingredients of the composition may be present in the following proportions, by weight:

	glycosaminoglycans	10 to 80 parts;
	glucosamine	10 to 80 parts; and
15	methyl sulphonyl methane	5 to 80 parts.

In a preferred form the composition has the following proportions, by weight, of the ingredients.

	glycosaminoglycans	25 parts;
20	glucosamine	20 parts; and
	methyl sulphonyl methane	50 parts.

Preferably the composition includes at least one of ascorbic acid and/or ascorbate.

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The ascorbic acid and/or ascorbate may be present in 0,1 - 20 parts by

5 weight.

Preferably 0,8 parts by weight of ascorbic acid and/or ascorbate are present.

10 The composition may include a suitable excipient as required.

The composition may include at least one of the following ingredients:

methionine;

lysine;

15 cystine;

cysteine;

other amino acids;

bioflavonoids;

vitamins;

20 plant or animal derivatives;

hyaluronon; and

hyaluronic acid.

The composition may include zinc, copper or manganese as chelates, salts
25 or in any other suitable form.

5 The composition may include probiotics, which may be present in any suitable derivative form.

The composition may be in the form of a liquid, a syrup, a powder tablet or a powder capsule or any other suitable form.

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The invention further provides a composition which includes a mixture of the following ingredients in the following relative proportions by weight:

	chondroitin sulphate	27 parts;
	glucosamine sulphate	22 parts;
15	methyl sulphonyl methane	49 parts;
	zinc	0,2 parts;
	manganese	0,2 parts;
	copper	0,06 parts;
	lysine	0,7 parts;
20	methionine	0,9 parts; and
	ascorbic acid	0,8 parts.

DESCRIPTION OF PREFERRED EMBODIMENT

A preferred example of the invention is provided by a composition which
25 includes a mixture of the following ingredients in the following relative proportions by weight:

5	chondroitin sulphate	27 parts;
	glucosamine sulphate	22 parts;
	methyl sulphonyl methane	49 parts;
	zinc	0,2 parts;
	manganese	0,2 parts;
10	copper	0,06 parts;
	lysine	0,7 parts;
	methionine	0,9 parts; and
	ascorbic acid	0,8 parts.

15 This composition has been found, through testing, to give meaningful relief to a significant proportion of a status group of arthritis sufferers.

The following trial was conducted:

20 Testing Procedure

Ten dogs of different breed and sex and of weight varying between 20 to 40 kg were each fed 10g of the composition on a daily basis. A control group of ten similar dogs were fed a 10g of a placebo also on a daily basis. The placebo was dextrose powder. All of these dogs were suffering from various degrees of osteoarthritic conditions. The animals were evaluated for improvement of the arthritic condition. Evaluation was done on the

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5 following criteria:

1. gait and movement;
2. pain sensation on joint manipulation;
3. appetite; and
4. general skin condition and wellbeing.

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Results

The animals fed with the composition showed increased mobility, reduced pain reaction to joint manipulation and increased exercise tolerance. Their appetites appeared to range from normal (as before), to slightly increased.

15 A general improvement in skin condition was seen with less hair shedding and reduced pruritis. Slight gastrointestinal upset was seen in one dog initially for two days but it subsequently subsided.

20 The animals fed with the control powder showed no change in behaviour, wellbeing, mobility or exercise tolerance.

Both groups of animals were kept under the same conditions as they were at the start of the trial. Exercise continued as before and there was no change in the rest of the diet.

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Without being bound by the ensuing explanation, it is believed that the

5 beneficial effects of the composition are attributable at least to the following factors:

- 10 (a) glycosaminoglycans in various forms, such as chondroitin sulphates, shark or bovine cartilage, and modified or synthetic materials of similar nature, are natural components of articular lubrication and connective tissue and are raw materials from which the body may synthesize cartilage. Hence the use of glycosaminoglycans can give considerable relief to arthritis sufferers, usually without any side effects;
- 15 (b) research indicates that glycosaminoglycans used with glucosamine or its salts, such as glucosamine sulphate, tend to promote the production of cartilage on bone surfaces which are in a suitable condition;
- 20 (c) glucosamine is necessary for the production of chondroitin sulphates and supports the production by the body of collagen;
- 25 (d) methyl sulphonyl methane is a natural anti-inflammatory agent, and is a valuable source of sulphur, an essential requirement for connective tissue in the body;

5 (e) ascorbic acid (or ascorbate) is essential for the synthesis of
proteoglycan and collagen which, in turn, are important for the
repair of connective tissue; and

10 (f) two of the eight essential amino acids, methionine (to produce
cystine) and lysine are also vital for the production of muscle tissue
and cartilage. It is therefore desirable to include at least one of the
following: methionine, cystine and lysine.

15 It is desirable to add traces of zinc to the composition for zinc deficiency
slows the synthesis of glycoaminoglycans and impairs the healing of
damage to connective tissues. The zinc should however be supplemented
with copper or manganese in a 3:1 ratio.

20 Further tests have shown that the inclusion of the amino acid cystine,
other amino acids, bioflavonoids, vitamins, plant or animal derivatives,
hyaluronon and hyaluronic acid contribute to the production of muscle
tissue, connective tissue and cartilage.

25 Cystine and other amino acids contribute to the production of cartilage.

Bioflavonoids are plant derivatives which have been shown to substantially

5 boost production of capillary walls which in turn improve the production of muscle tissue, connective tissue and cartilage.

Various vitamins for example, vitamin C, are essential for the production of connective tissue and cartilage.

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Glycoaminoglycans are found in various plant or animal derivatives such as shark or bovine cartilage as mentioned before.

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Hyaluronon and hyaluronic acid have been found to be present during, and to contribute to, the production of cartilage and connective tissue.

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As indicated the composition has been found, through testing, to provide relief from pain, and to possess restorative capabilities, for sufferers of arthritis and other bone degenerative diseases. The optimum dosage for patients can however vary widely from case to case.

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For example, a daily dosage of about 200mg of the composition per kilogram of bodyweight will provide at least a degree of relief for a substantial proportion of subjects. The daily dosage of the composition may be taken by way of three tablets, taken one at a time at eight hour intervals.

5 It is to be understood that any suitable excipient may be used with the composition.

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CLAIMS

1. A pharmaceutical composition for the treatment of bone degenerating diseases which includes a mixture of the following ingredients:

glycosaminoglycans;

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glucosamine; and

methyl sulphonyl methane

2. A composition according to claim 1 wherein the glucosamine is provided as a salt derivative of glucosamine.

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3. A composition according to claim 1 or 2 wherein the glycosaminoglycans are provided in the form of at least one of the following:

chondroitin sulphates;

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mixed glycosaminoglycans;

shark or bovine cartilage;

other similar animal derivatives;

synthetic products;

or sulphated products.

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4. A composition according to claim 1, 2 or 3 wherein the ingredients

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are present in the following proportions, by weight:

glycosaminoglycans	10 to 80 parts;
glucosamine	10 to 80 parts; and
methyl sulphonyl methane	5 to 80 parts.

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5. A composition according to claim 4 which has the following proportions, by weight, of the ingredients:

glycosaminoglycans	25 parts;
glucosamine	20 parts; and
methyl sulphonyl methane	50 parts.

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6. A composition according to any one of claims 1 to 5 which includes at least one of ascorbic acid and/or ascorbate.

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7. A composition according to claim 6 wherein the ascorbic acid and/or ascorbate are present in 0,1 - 20 parts by weight.

8. A composition according to claim 7 wherein the ascorbic acid and/or ascorbate are present in 0,8 parts by weight.

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9. A composition according to any one of claims 1 to 8 which includes a suitable excipient as required.

- 5 10. A composition according to any one of claims 1 to 9 which includes
at least one of the following:
methionine;
lysine;
cystine;
10 cysteine;
other amino acids;
bioflavonoids;
vitamins;
plant or animal derivatives;
15 hyaluronon; and
hyaluronic acid.
11. A composition according to any one of claims 1 to 10 wherein the
composition includes zinc, copper or manganese as chelates, salts
20 or in any other suitable form.
12. A composition according to any one of claims 1 to 11 wherein the
composition includes probiotics, or derivatives of probiotics.
- 25 13. A composition according to any one of claims 1 to 12 which is in the
form of a liquid, a syrup, a powder tablet or a powder capsule or any

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other suitable form.

14. A composition which includes a mixture of the following ingredients in the following proportions by weight:

	chondroitin sulphate	27 parts;
10	glucosamine sulphate	22 parts;
	methyl sulphonyl methane	49 parts;
	zinc	0,2 parts;
	manganese	0,2 parts;
	copper	0,6 parts;
15	lysine	0,7 parts;
	methionine	0,9 parts; and
	ascorbic acid	0,8 parts.

15. A composition substantially as herein described with reference to the example.

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16. A composition according to claim 1 wherein the glycosaminoglycans and the glucosamine are provided in the form of derivatives of the glycosaminoglycans and glucosamine.

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17. A composition according to claim 16 wherein the

5 glycosaminoglycans are in the form of a salt derivative or an ester derivative of the glycosaminoglycans.

18. A composition according to claim 16 or 17 wherein the glycosamine is provided as an ester derivative of the glycosamine.

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19. A composition according to claim 16, 17 or 18 wherein the glycosaminoglycans are provided in the form of at least one of the following:

chondroitin sulphates;

15 mixed glycosaminoglycans;

shark or bovine cartilage;

other similar animal derivatives;

synthetic products;

or sulphated products.

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20. A composition according to claim 16, 17 or 18 wherein the ingredients are present in the following proportions, by weight:

glycosaminoglycans 10 to 80 parts;

glucosamine 10 to 80 parts; and

25 methyl sulphonyl methane 5 to 80 parts.

- 5 21. A composition according to claim 20 which has the following proportions, by weight, of the ingredients:

glycosaminoglycans	25 parts;
glucosamine	20 parts; and
methyl sulphonyl methane	50 parts.

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22. A composition according to any one of claims 16 to 21 which includes at least one of ascorbic acid and ascorbate.

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23. A composition according to claim 22 wherein the ascorbic acid and/or ascorbate are present in 0,1 - 20 parts by weight.

24. A composition according to claim 23 wherein the ascorbic acid and/or ascorbate are present in 0,8 parts by weight.

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25. A composition according to any one of claims 16 to 24 which includes a suitable excipient as required.

26. A composition according to any one of claims 16 to 25 which includes at least one of the following:

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lysine;
cystine;

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cystine;

cysteine;

other amino acids;

bioflavonoids;

vitamins;

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plant or animal derivatives;

hyaluronon; and

hyaluronic acid.

27. A composition according to any one of claims 16 to 26 wherein the

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composition includes zinc, copper or manganese as chelates, salts
or in any other suitable form.

28. A composition according to any one of claims 16 to 27 wherein the
composition includes probiotics, or derivatives of probiotics.

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29. A composition according to any one of claims 16 to 28 which is in
the form of a liquid, a syrup, a powder tablet or a powder capsule or
any other suitable form.

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5 DATED this 27th day of JUNE 2000

A handwritten signature in dark ink, appearing to read 'M. J. Rad', is written over a horizontal line.

10 McCALLUM, RADEMEYER & FREIMOND
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